SECTIONS OF FEDERAL FOOD, DRUG, AND COSMETIC ACT INVOLVED IN VIOLATIONS REPORTED IN D.D.N.J. NOS. 6441–6460

Adulteration, Section 501(b), the article purported to be and was represented as a drug, the name of which is recognized in an official compendium (United States Pharmacopoeia or National Formulary), and its strength differed from the standard set forth in such compendium; Section 501(c), the article was not subject to the provisions of Section 501(b), and its quality fell below that which it purported or was represented to possess.

Misbranding, Section 502(a), the labeling of the article was false and misleading; Section 502(b), the article was in package form, and it failed to bear a label containing (1) the name and place of business of the manufacturer, packer, or distributor, and (2) an accurate statement of the quantity of the contents in terms of weight, measure or numerical count; Section 502(c), the article failed to bear on its label or labeling, all words, statements, and other information required by or under authority of the Act to appear on the label or labeling in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use; Section 502(e)(1), the article was a drug not designated solely by a name recognized in an official compendium, and its label failed to bear the common or usual name of the drug; Section 502(f), the labeling of the article failed to bear (1) adequate directions for use, and (2) adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users; Section 502(j), the article was dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling; Section 502(l), the article was composed wholly or in part of bacitracin, and was not from a batch with respect to which a certificate or release had been issued pursuant to Section 507; and Section 503(b)(4), the article was a drug subject to Section 503(b)(1), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DRUG AND DEVICE ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

6441. Distilled water and hypodermic kits. (F.D.C. No. 45071. S. Nos. 31–110/2 R.)

QUANTITY: Unknown quantities of a clear liquid in unlabeled glass ampuls represented to be the *Koch Treatment*, and unknown quantities of hypodermic kits, each kit containing a glass hypodermic syringe and needle, at Palestine, Tex., in possession of Reynolds Clinic.

SHIPPED: On unknown dates from places outside the State of Texas.

ACCOMPANYING LABELING: Leaflets entitled "The Reynolds Clinic * * * Since 1941," "Koch's Glyoxylide 12X," "The Koch Treatment (Glyoxylide) in Alcoholic Neuritis * * * 3. Arthritis," "The Koch Treatment (Glyoxylide) in Alcoholic Neuritis * * * 2. Bursitis, Sciatica, Toxic Liver and Arthritis," "Order Form"; brochures entitled "Glyoxylide Case Reports" and "The Koch Treatment Patients Diet"; and a mimeographed slip of paper reading in part "Glyoxylide 12X Sterile * * * O=C=C=O."

LIBELED: 11–2–60, E. Dist. Tex.

CHARGE: *Clear liquid in ampuls.* 502(a)—while held for sale, the accompanying labeling of the article contained false and misleading representations that

the article was adequate and effective in the treatment and prevention of cancer and other diseases and conditions in man; 502(b)(1)—the article failed to bear a label containing the name and place of business of the manufacturer, packer, or distributor; 502(e)(1)—the label of the article failed to bear the common or usual name of the article, namely, *distilled water;* 502(f)(1)—the label of the article failed to bear adequate directions for use in that the directions for use with respect to dosage and frequency and duration of administration of the article were not adequate for the treatment or prevention of the diseases and conditions for which the article was intended, including in particular, cancer; 502(f)(1)—the labeling of the article failed to bear adequate directions for use and it was not exempt from such requirement since it was in the possession of persons who were not regularly and lawfully engaged in the manufacture, transportation, storage, or distribution of prescription drugs, and since the article was not to be dispensed upon prescription; 502(f)(2)—the labeling of the article failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health and against unsafe methods of administration; and 502(j)—the article was dangerous to health when used with the frequency prescribed, recommended, and suggested in its label.

Hypodermic kits. 502(f)(1)—the labeling of the article failed to bear adequate directions for use; 502(f)(2)—the labeling of the article failed to bear adequate warnings against use in those pathological conditions where its use may be dangerous to health and against unsafe methods of application; and 502(j)—the article was dangerous to health when used with the frequency prescribed, recommended, and suggested in its labeling.

DISPOSITION: 1–4–61. Default—delivered to the Food and Drug Administration.

DRUG REQUIRING CERTIFICATE OR RELEASE, FOR WHICH NONE HAD BEEN ISSUED

6442. Bacitracin. (F.D.C. No. 45072. S. Nos. 32–340 R, 32–451 R, 33–362/4 R, 36–101/2 R.)

QUANTITY: 734 ctnd. vials at New York, N.Y.

SHIPPED: Between 8–11–60 and 8–16–60, from Philadelphia, Pa., by Philadelphia Ampoule Laboratories.

LABEL IN PART: (Ctn. and ampul) "No. 2005 Bacitracin U.S.P. Sterile 50,000 Units For Intramuscular or Topical Use * * * Philadelphia Ampoule Laboratories, Philadelphia 23, Pa. * * * Lot No. 8018 Exp. Date 9–62."

LIBELED: 11–16–60, S. Dist. N.Y.

CHARGE: 501(b)—when shipped, the strength of the article differed from the strength set forth in the United States Pharmacopoeia for *bacitracin;* 502(a)—the label statement "50,000 Units" was false and misleading as applied to a product containing less than 50,000 units of *bacitracin* per ampul; and 502(l)—the article purported to be, and was represented as, a drug composed wholly or in part of *bacitracin,* and it was not from a batch with respect to which a certificate or release had been issued pursuant to 507.

DISPOSITION: 12–27–60. Default—destruction.